The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board

Paper No. 40

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte STEVEN MCDANIEL, FRANK M. RAUSHEL, and JAMES R. WILD

Appeal No. 1997-2138
Application No. 08/252,384

HEARD: November 14, 2000

Before WINTERS, ROBINSON, and ADAMS, Administrative Patent Judges.

ROBINSON, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 53 through 64, which are all of the claims pending in the application.

Claim 53 is illustrative of the subject matter on appeal and reads as follows:

53. A method for detoxifying an organophosphorus compound comprising exposing said compound to recombinant bacterial organophosphorus acid anhydrase.

The references relied upon by the examiner are:

Grot et al. (Grot)	4,518,650	May 21, 1985
Gottlieb	4,781,959	Nov. 1, 1988

Stryer, "Thrombin is Homologous to Trysin," Biochemistry, Chapter 8, page 197 (1975)

Munnecke, "Properties of an Immobilized Pesticide-Hydrolyzing Enzyme," Applied and Environmental Microbiology, Vol. 33, No. 3, pp. 503-07 (Mar. 1977)

Schulz et al. (Schulz), "Patterns of Folding and Association of Polypeptide Chains," Principles of Protein Structure, Chapter 5, pp. 66-67 (1979)

Munnecke, "The Use of Microbial Enzymes for Pesticide Detoxification," Microbial Degradation of Xenobiotics and Recalcitrant Compounds," pp. 251-69 (1981)

Webster's New Riverside University Dictionary, pp. 390, 760, and 1107 (1984)

The Merck Index, "Tenth Edition, page 1058 (1983)

McDaniel (McDaniel (AZ)), "Plasmid-Mediated Degradation of Organophosphate Pesticides," PhD Dissertation, pp. 111-64 (Dec. 1985)

Wild et al. (Wild), "Cloning, Sequencing and Characterization of OPD Genes and Their Broad-Spectrum Organophosphate Hydrolases From Soil Bacteria," Proceedings of the 1986 U.S. Army Chemical Research, Development and Engineering Center Scientific Conference on Chemical Defense Research, pp. 629-34 (Nov. 1986)

Chaudhry et al. (Chaudhry), "Isolation of a Methyl Parathion-Degrading Pseudomonas sp. That Possesses DNA Homologous to the opd Gene from a Flavobacterium sp.," Applied and Environmental Microbiology, Vol. 54, No. 2, pp. 288-93 (Feb. 1988)

McDaniel et al. (McDaniel (BY)), "Cloning and Sequencing of a Plasmid-Borne Gene (opd) Encoding a Phosphotriesterase," Journal of Bacteriology, Vol. 170, No. 5, pp. 2306-311 (May 1988)

Harper et al. (Harper), "Dissimilar Plasmids Isolated from Pseudomonas diminuta MG and a Flavobacterium sp. (ATCC 27551) Contain Identical opd Genes," Applied and Environmental Microbiology, Vol. 54, No. 10, pp. 2586-589 (Oct. 1988)

Mulbry et al. (Mulbry), "Parathion Hydrolase Specified by the Flavobacterium opd Gene: Relationship between the Gene and Protein," Journal of Bacteriology, Vol. 171, No. 2, pp. 6740-746 (Dec. 1989)

Hawley's Condensed Chemical Dictionary, Twelfth Edition, page 857 (1992)

Watson et al. (Watson), "Recombination at the Molecular Level," Molecular Biology of the Gene, Fourth Edition, Chapter 11, page 313 (1993)

Grounds of Rejection

Claims 53 through 64 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on an inadequate written description for practicing the invention.

Claims 53 through 64 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on a disclosure which is not enabling for the full scope of the claimed subject matter.

Claims 53 through 64 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite and failing to particularly point out the subject matter which applicants regard as their invention.

Claims 53, 54, and 58 through 63 stand rejected under 35 U.S.C. § 102(a) or, alternatively, under 35 U.S.C. § 103. As evidence of anticipation/obviousness, the examiner relies upon McDaniel (BY) or Harper.

Claims 53, 58, and 60 stand rejected under 35 U.S.C. § 102(b). As evidence of anticipation the examiner relies upon Wild.

Claims 61 through 63 stand rejected under 35 U.S.C. § 102(b) or, alternatively, under 35 U.S.C. § 103. As evidence of anticipation/obviousness, the examiner relies upon Wild or McDaniel (AZ).

Claims 53, 54, and 60 stand rejected under 35 U.S.C. § 102(b). As evidence of anticipation, the examiner relies upon McDaniel (AZ).

Claims 53 through 54 and 59 through 64 stand rejected under 35 U.S.C. § 103. As evidence of obviousness the examiner relies upon Munnecke (AW), Munnecke (CD), McDaniel (BY), Wild, and Gottlieb.

Claims 55 through 57 stand rejected under 35 U.S.C. § 103. As evidence of obviousness the examiner relies upon Munnecke (AW), Munnecke (CD), McDaniel (BY, Wild, Gottlieb, and Grot.

We reverse the rejections of claims 53 through 64 under 35 U.S.C. § 112, first and second paragraphs, affirm the rejections of the claims as unpatentable under 35 U.S.C. § 102(a) and 102(b), and find it unnecessary to reach the rejections of the claims under 35 U.S.C. § 103 for reasons set forth herein.

Discussion

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims and to the respective positions articulated by the appellants and the examiner. We make reference to the Examiner's Answer of February 7, 1996 (Paper No. 32) for the examiner's reasoning in support of the

rejections and to the appellants' Appeal Brief filed August 16, 1995 (Paper No. 27) and Reply Brief filed November 24, 1995 (Paper No. 31) for the appellants' arguments thereagainst.

Grouping of the claims

At page 11 of the Brief on Appeal (Brief), appellants state that "[c]laims 53 - 64 are all properly of a single group." We interpret this to mean that, as to the questions of patentability raised by this appeal, the claims stand and fall together. Therefore, we have limited our consideration of the issues of patentability raised by this appeal as they apply to claim 53 as representative of claims 53 through 64 (37 CFR § 1.192 (5) (1995)). Thus, the determination reached in this decision as to the patentability of claim 53 is considered dispositive of the question of patentability of the remaining claims.

Claim Interpretation

Claim 53 is directed to a method for detoxifying an organophosphorus compound comprising exposing said compound to a recombinant bacterial organophosphorus acid anhydrase. Appellants explain, at page 27 of the Appeal Brief, that there is but one enzyme known which fits the description of the specification of the organophosphorus acid anhydrase designated in the claim and that, to appellants knowledge, this enzyme even if isolated from different strains of bacteria, has an identical amino acid sequence and identical activities. It follows that the recombinant enzyme of claim 53 is the same enzyme which occurs in nature in certain bacteria from which the described DNA has been

isolated[1]. The claims before us are not directed to the DNA which encodes the claim designated anhydrase or to recombinant organisms which have been transformed with this DNA, but to the use of a particular enzyme having the ability to detoxify organophosphorus compounds. While some claims provide that the recombinant anhydrase is produced by a transformed organism which includes the specified DNA coding sequence, these are process of preparation limitations and, in our opinion, do not serve to distinguish the enzyme of the claim from another enzyme from a different source which has the ability to detoxify organophosphorus compounds. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 697, 227 USPQ 964, 965-66 (Fed. Cir. 1985). Here, the enzyme which is used in the claimed method differs from the enzyme in nature, only in being recombinantly produced.

The rejections under 35 U.S.C. § 112

Claims 53 through 64 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on an inadequate written description for practicing the claimed invention. To the extent that we understand the examiner's position, this rejection appears to be

[1] This was confirmed by appellants' representative at the Oral Hearing of November 14, 2000.

based on two separate propositions. The first is that (Answer, paragraph bridging pages 15-16):

> there are apparently at least three different references all directed to the apparent identical genetic material where no one reference indicates a sequence identity for the apparently identical genetic material and therefore, a query is raised as to what genetic material is disclosed as coding for the organophosphorous acid anhydrase used in the process of detoxification as each is the same but different and given that there are three disparate sequences from apparently the identical material . . . it is not clear that one of ordinary skill in the art using solely the disclosure in the application would have obtained the appropriate identical DNA encoding the organophosphorous acid anhydrase which is defined by the amino acid sequence of Figure 1.

The second proposition is that (Answer, page 18):

> the present specification fails to disclose the process as occurring simply by exposing the enzyme to the compound. . . simply "exposing" does not necessarily result in a detoxified compound as an organophosphorous compound which is not a substrate for the enzyme is not detoxified nor does "exposing" the compound to an inactive organophosphorous anhydrase enzyme result in a detoxified compound. . . .

A specification of a patent application is presumed to comply with the enablement requirement of 35 U.S.C. § 112, first paragraph. An examiner may reject claims in a patent application on the basis of an alleged failure of the applicants to comply with the enablement requirement if the examiner can establish by a preponderance of the evidence that there is reason to doubt the objective truth of the statements contained in the specification. In re Marzocchi, 439 F.2d 220, 223-24, 169 USPQ 367, 369-70 (CCPA 1971). In our opinion, the examiner has not sustained his burden in making the present

enablement rejection. In explaining the initial basis of this rejection, the examiner has not premised this rejection on what is disclosed by applicants' application, but on what is not disclosed. That the record indicates that there is possible disagreement as to the true sequence of the DNA which would encode a particular enzyme does not, standing alone establish that the present disclosure does not support the claimed invention. Simply put, the examiner has failed to address those factors which would reasonably support a conclusion that the present disclosure would not enable one skilled in this art to practice the claimed invention without undue experimentation. See In re Wands, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988).

To the extent that the rejection represents a "potential" rejection alleging that the written description does not support the presently claimed invention, we note simply that while appellants may have proffered a substitute Figure 1 which would have altered the DNA sequence disclosed therein, and presumably the amino acid sequence of the enzyme, on the record before us, the amendment has neither been presented or entered by the examiner. Thus, there is no basis to question whether the disclosure in support of the invention reasonably describes the presently claimed invention. See In re Vas Cath, Inc. v. Mahurkar, 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991).

As to the second basis of concern expressed by the examiner, we note that the generalities and speculation offered by the examiner, as to whether "exposing" an organophosphorous compound to a recombinant bacterial organophosphorous acid

anhydrase as required by claim 53 would result in detoxification, are insufficient, standing alone, to establish that a disclosure in support of a claimed invention is not enabling. See In re Wands, supra.

Thus, the examiner has failed to provide those facts and evidence which would reasonably establish a prima facie case of unpatentability as to the present claims. We, therefore, reverse this rejection of claims 53 through 64 under 35 U.S.C. § 112, first paragraph.

The examiner has, additionally, rejected claims 53 through 64 under 35 U.S.C. § 112, first paragraph urging that the "disclosure is enabling only for claims limited to the specifically disclosed compounds such as parathion, paraoxon, and methyl parathion and the specifically disclosed enzyme as defined by the amino acid sequence shown in specification figure 1 . . . because the present specification discloses an enzymatic reaction resulting in degradation of the organophosphorous compounds . . . [and] the present specification fails to disclose the process as occurring simply by exposing the enzyme to the compound." (Answer, paragraph bridging pages 18-19). Here the issue presented is whether appellants' disclosure would have enabled one skilled in the art to make and use the claimed invention throughout its scope without undue experimentation. The Patent and Trademark Office (PTO) bears the initial burden of providing reasons for doubting the objective truth of the statements made by applicants as to the scope of enablement. Only when the PTO meets this burden, does the burden shift to applicants to provide suitable evidence indicating that the specification is enabling in a manner commensurate in scope with the protection sought by the claims. In re Marzocchi, supra.

On the record before us, we find that the examiner's statements, in support of this rejection, fall short of the requirement set forth above. The examiner has not provided sufficient evidence or reasons to establish that one skilled in the art would doubt the statements of the disclosure in support of the claimed invention relating to the exposing toxic organophosphorus compounds to the recombinant organophosphorus acid anhydrase in order to achieve detoxification of those compounds. That the examiner might be able to envision situations where the claimed invention would not work, is insufficient, standing alone to support a conclusion that the claimed invention is not enabled throughout it claimed scope. For example, to interpret the organophosphorus compound of claim 53 to encompass DNA seems unreasonable when the specification is read as one skilled in this art would read it. The examiner has provided no evidence which would reasonably establish that DNA is an organophosphorus compound which one would want to "detoxify" in the manner presently claimed. Similarly, as to the use of an inactive enzyme to detoxify such compounds, the specification reasonably appears to describe the recombinant bacterial organophosphorus acid anhydrase and the examiner has provided no evidence which would suggest that there are compounds which would fall within the scope of claim 53 which would be inactive. It is not a function of the claims to specifically exclude possible inoperative combinations. Atlas Powder Co. v. E.I. Dupont De Nemours & Co., 750 F.2d at 1576, 224 USPQ at 414 citing In re Dinh-Nguyen, 492 F.2d 856, 858-59, 181 USPQ 46, 48 (CCPA 1974). Of course, if the number of

inoperative embodiments becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be nonenabled. However, that has not been shown to be the case here. A conclusion of lack of enablement should be based on the evidence available and should reasonably establish that the disclosure in support of the claimed subject matter would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

Thus, to the extent that we understand the examiner's position in this rejection, the examiner has failed to make those factual findings which must be made before a conclusion of "lack of enablement" may properly be reached. Therefore, this rejection of claims 53-64 under 35 U.S.C. § 112, first paragraph, is reversed.

The examiner has rejected claims 53 through 64 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. The examiner contents that "[c]laim 53 is incomplete as there is no stated result of the effect of exposing the compound with the organophosphorous acid anhydrase." (Answer, page 19).

We point out that it is well established that "definiteness of the language employed must be analyzed, not in a vacuum, but always in light of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of

skill in the pertinent art." In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971). The purpose of the second paragraph of Section 112 is to basically insure, with a reasonable degree of particularity, an adequate notification of the metes and bounds of what is being claimed. See In re Hammack, 427 F.2d 1378, 1382, 166 USPQ 204, 208 (CCPA 1970). When viewed in light of this authority, we do not agree with the examiner that the metes and bounds of claims 53 through 64 can not be determined when read in light of the specification and as one skilled in this art would interpret them. The examiner has the initial burden of demonstrating indefiniteness of the claims. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Here, the examiner has not convincingly demonstrated that one of ordinary skill would not readily recognize the metes and bounds of the rejected claims. It would appear from the examiner's statement of the rejection that his concern relates to the scope of the subject matter claimed rather than whether the scope of the claim is ascertainable. However, this is an issue appropriately raised under 35 U.S.C. § 112, first paragraph. In our opinion, the examiner has not established that the rejected claims, read in light of the specification and interpreted by one skilled in this art, would not reasonably apprise such a skilled person what is encompassed by the claims. We, therefore, reverse the rejection of claims 53 - 64 under 35 U.S.C. § 112, second paragraph.

The rejections under 35 U.S.C. § 102(a) and § 102(b)

Representative claim 53 stands rejected under 35 U.S.C. § 102(a) as anticipated by McDaniel (BY) or Harper and under 35 U.S.C. § 102(b) as anticipated by Wild or

McDaniel (AZ). The examiner has relied upon each of these references as disclosing a recombinantly derived organophosphorous acid anhydrase which is used to detoxify organophosphorous compounds. See McDaniel (BY) at pages 2306, 2307; Harper at page 2586; Wild at pages 628-630; and McDaniel (AZ) at pages 45, 62, and 101+.

Anticipation requires the disclosure, in a single prior art reference, of each element of the claim under consideration. W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 1554, 220 USPQ 303, 313 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). In considering McDaniel (BY), Harper, Wild, and McDaniel (AZ), we agree that each reference describes the use of a recombinant bacterial organophosphorus acid anhydrase for the detoxification of an organophosphorus compound. Each of the references provide a description of the claimed process which would reasonably appear to meet all limitations of claim 53 and thus each serves to establish a prima facie case of anticipation of the claimed subject matter.

In rebuttal, appellants argue that neither McDaniel (BY) nor Harper are prior art to the claimed invention. Yet, both were published prior to the earliest filing date to which the present invention could be entitled. Thus, both references constitute prior art under 35 U.S.C. § 102 (a) since they are each "a printed publication in this . . . country, before the invention thereof by the applicant for patent," (35 U.S.C. § 102(a)). On the record before us, appellants have not filed a declaration under 35 U.S.C. § 131 to antedate the two publications. The appellants urge that In re Katz, 687 F.2d 450,

215 USPQ 14 (CCPA 1982) would establish that a declaration by the co-authors are not necessary to establish a date of invention prior to the publication date of the references. (Brief, pages 30-31). In addition, appellants urge that the Declaration of Invention filed with the present application is in accord with Katz and combined with statements of record to indicate that the remaining authors of the two references were not inventors should be regarded as sufficient to overcome the rejection under 35 U.S.C. § 102(a). However, we note that in Katz, the appellant's Declaration of the Invention further indicated that (In re Katz, 687 F.2d at 452, 215 USPQ at 15.):

> He is co-author of a report in the proceedings of the National Academy of Science, U.S.A., Volume 73, No. 6, Pages 2091-2095, June, 1976, communicated to the National Academy of Science by Albert H. Coons, a member of said Academy, on March 8, 1976, that he is the sole inventor of the subject matter which is disclosed in said publication in the proceedings of the National Academy of Science and disclosed and claimed in the application submitted herewith." [Emphasis in the original].

The declaration present in this application does not contain a similar averment as to inventorship which, additionally, identifies the publications in question. Thus, standing alone, the Declaration of the Invention, included with the present application when filed, which does not explicitly identify the prior publication and does not state that the appellants are the inventors of the subject matter disclosed in the publications in question, is not sufficient evidence to establish that the subject matter described in McDaniel (BY) and Harper is the work of the present appellants. Appellants' proffer of

a disclaiming affidavit from both Harper and Miller is noted. (Brief, pages 32 and 33). However, this evidence is not now of record and thus can not be weighed as evidence in the present appeal.

In addressing the rejection under 35 U.S.C. § 102(b) over Wild, the appellants urge that Wild does not teach the DNA sequence of the opd gene nor does it anticipate the difficulty that the present inventors encountered in obtaining the sequence and the initiation codon necessary for subsequent manipulation of the opd gene for purposes of the expression of the gene. (Brief, pages 33-34). However, as we have stated in interpreting claim 53, the claimed invention is not directed to the opd gene or the use thereof. That appellants may have, alternatively, defined the claim designated hydrolase in terms of the DNA which encodes it, does not serve to demonstrate that the enzyme is not the enzyme described in each of these references. Appellants have offered no evidence that the anhydrase encoded by the opd gene described in the specification differs from the anhydrase explicitly described in McDaniel (BY), Harper, or Wild. In the absence of such evidence, the information and arguments concerning the opd gene or the specific DNA used to encode a given anhydrase are of little value in attempting to establish that the recombinant bacterial organophosphorous acid anhydrase explicitly described by McDaniel (BY), Harper and Wild is not the same as that called for in claim 53.

Appellants' arguments directed to the question of whether McDaniel (AZ) anticipates the claimed subject matter is similarly flawed. (Brief, page 35). That the opd gene is not disclosed is not determinative of the question whether the reference anticipates the present claim 53. To the extent that appellants argue that the rejected claims require the recombinant DNA sequence of the invention, we would note simply that claim 53 does not require the DNA sequence. As we have noted above, the appellants have offered no evidence which would reasonably establish that the enzyme, resulting from the expression of the isolated opd gene having the sequence of Figure 1 of the specification, differs from the enzyme described by the references relied upon by the examiner.

Thus, on this record, when we weigh the facts and evidence provided by the examiner in support of the rejection of the claimed invention under 35 U.S.C. § 102 over McDaniel (BY), Harper, Wild, and McDaniel (AZ) against the facts and evidence provided by the appellants, we conclude that, on balance, the evidence in favor of anticipation outweighs the evidence provided by the appellants. Therefore, we affirm the rejections of representative claim 53. Having determined that representative claim 53 is unpatentable under 35 U.S.C. § 102, it follows that the remaining claims are similarly unpatentable for the reasons stated.

Having determined that the claims in this application are unpatentable over the prior art represented by McDaniel (BY), Harper, Wild, and McDaniel (AZ), we find is unnecessary to separately consider the rejection of the claims under 35 U.S.C. § 103.

Summary

The examiner's determination that the claims pending in this application are unpatentable under 35 U.S.C. § 112, first and second paragraphs is reversed. The examiner's determination that the claims pending in this application are unpatentable under 35 U.S.C. § 102 (a) and/or 35 U.S.C. § 102(b) is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Sherman D. Winters)
Administrative Patent Judge)
)
)
)
Douglas W. Robinson) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
) INTERFERENCES
)
)
Donald E. Adams)
Administrative Patent Judge)

Appeal No. 1997-2138
Application No. 08/252,384

C. Steven McDaniel
McDaniel & Associates, P.C.
P.O. Box 2244
Austin, TX 78768-2244

DWR/cam